REMARKS:

In the International Search Report, the Authorized Officer cited U.S. Patent No. 5,567,444 (the Hei et al. patent) and U.S. Patent No. 5,443,801 (the Langford patent) as the only references of any relevance to the claims of the present case. In particular, the Authorized Officer found that the claimed invention could not be considered to involve an inventive step in view of the Hei et al. and Langford patents.

In response, the applicant has cancelled claims 1-13, amended claims 14, 21, and 27, added a new claim (29), and submits herewith remarks clarifying the differences between the present invention and the cited art.

The Langford Patent generally discloses a cleansing/sterilizing apparatus for sterilization of various complex and reusable medical and dental instruments (Abstract). More specifically, Langford's apparatus washes with detergent dissolved in purified water, rinses by means of purified water, sterilizes by means of ozonated and purified water, and dries by means of "ozonated/deozonated sterile warm dry oxygen or a sterile inert gas" (Col. 3, lines 47-51).

Thus, according to the teachings of Langford, ozone rinsing is always related to the primary sterilization step that takes place just after an item is cleaned (see, for example, Col 6, lines 47-52 "Sterilization using ozone is effective for all ocular pathogens including viruses, bacteria, fungus, and most importantly amoebae."). Langford does not, however, disclose or suggest an "overkill rinse" of an *already cleaned and sterilized* item.

Hei et al. discloses a cleaning and sanitizing method for soiled solid surfaces that involves first contacting the surfaces with aqueous ozone having a pH greater than 7 then quenching the ozone and simultaneously sanitizing the surfaces through the application of hydrogen peroxide or other chemical sterilant (Abstract). Thus, the invention of Hei et al. is limited to an ozone pretreatment followed by *immediate* quenching of ozone to ensure rapid degradation for health-related reasons ("Thus, although ozone has been demonstrated to be effective in cleaning soil from solid surfaces in plant facilities and in clean-in-place process facilities, there is a need in the industry to reduce the health hazard to workers due to inhalation or

contacting with ozone by reducing the level of ozone in the immediate vicinity of application." Col. 1, lines 41-47). Moreover, Hei et al. do not at all address the problem of filtered water treatment or minimizing cross contamination through on "overkill rinse" with ozone. Nor could such a treatment be suggested as ozone is quenched immediately after Hei et al.'s pretreatment step occurs.

The disclosure of the present invention emphasizes the "overkill" aspect of a final rinse with ozone ("Preferably, at least the final rinse water used in any protocol should be ozonated at the point of application to prevent re-contamination of the cleaned and sterilized item. This is especially true if the sterilization method relies on the use of filtered tap water." Page 05, Summary of the Invention). Therefore, in contrast with Langford and Hei et al., all pending independent claims in the present case recite limitations relating to an additional or "overkill" ozone rinsing step, i.e., additionally rinsing an *already cleaned and high-level disinfected item* (claims 14 and 21) or rinsing the components of a sterilizing apparatus (claim 27) with ozone. Accordingly, independent claim 14 recites, in relevant part:

> d. applying a chemical sterilizing agent to said clean item to achieve high-level disinfection,
> e. rinsing the high-level disinfected item with water; and
> f. rinsing the high-level disinfected item with ozone to substantially degrade any remaining chemical residue and biomatter on or in said disinfected item.

Similarly, independent claim 21 recites, in relevant part: "a. rinsing said cleaned and high-level disinfected item with water; and b. flushing said item with ozone."

Finally, independent claim 27 recites:

> A method of preventing cross-contamination of components within a sterilizing apparatus, comprising:
> a. high-level disinfecting an item placed within said sterilizing apparatus according to a predetermined method; and
> b. flushing said components with ozone after the completion of step a.

The applicant respectfully submits that neither of the cited art patents describes or suggests these limitations.

That these claims do not recite an obvious variation on Langford and Hei et al.'s inventions is further demonstrated by fact that, despite the existence of numerous cleaning and sterilizing apparatus and methods for reusable items (in addition to those described by Langford and Hei et al.), no invention has thus far reliably addressed the problem of ensuring that cleaned and sterilized items (especially medical scopes) are contaminant free. Such has been underscored by a recent article entitled "Widely used sterilizer under attack" (published in January 21, 2003 edition of the newspaper USA Today, submitted herewith as part of applicant's Information Disclosure Statement). This article describes a fatal outbreak of bacterial infection that was linked to the improper sterilization of hospital bronchoscopes. Despite the hospital's use of one of the most popular sterilizing systems, tests performed by the United States Centers for Disease Control and Prevention found bacteria on the system's water filters and in its rinse water. This and other infection outbreaks has led to continuing controversy over how best to clean and sterilize used endoscopes.

The contaminants typically found on tubular medical items, such as endoscopes, are especially difficult to remove. In addition to fecal mater, loose cellular debris, blood and blood products, viruses, and bacteria, an endoscope can be coated with various hydrophobic films, such as "biofilm" material. A biofilm typically comprises cells, both dead and alive, cell debris and extracellular polymer substances. Once biofilm is formed by microorganisms (including bacteria, fungi, and protozoans), these microorganisms can colonize and replicate on the interior surfaces of tubing, forming a protective slime layer known as a "glycocalx" that is especially difficult to remove.

Yet, while many medical instruments today are routinely cleaned, disinfected, and reused, experts in the field recently have warned that some of the more difficult to clean and sterilize medical items are putting people at risk.

Indeed, one expert has stated that there are no independent published reports or data anywhere in the medical literature that show liquid chemical sterilants (or any other method/process/agent) can be used to reliably "sterilize" flexible endoscopes or other complex, lumened instruments (See Comments by L. Muscarella (Custom Ultrasonics) on AAMI TIR7:1999, Chemical Sterilants and Sterilization Methods: A Guide to Selection and Use, submitted herewith as part of applicant's Information Disclosure Statement).

Furthermore, Kovacs *et al.* reports that a strain of *Pseudomonas aeruginosa* has been repeatedly isolated from tap water used for cleaning and rinsing endoscopes and appears to be responsible for three separate clinical episodes of endoscopic retrograde cholangio-pancreatography (ERCP)-associated cholangitis over an 11-yr period. These authors also conclude that the organism is resistant to a commonly used sterilant because it was recovered from a variety of endoscopes that had undergone stringent reprocessing protocols (see Kovacs BJ, et al. "Efficacy of various disinfectants in killing a resistant strain of *Pseudomonas aeruginosa* by comparing zones of inhibition: Implications for endoscopic equipment reprocessing," *Am J Gastroenterol* 1998;93:2057-9). Thus, there has existed a genuine need for "overkill" sterilization to help ensure that even chemical-resistant pathogens are effectively eliminated that is fulfilled by the present invention.

Even the simple act of rinsing medical items with filtered water after cleaning or sterilization has been called into question. After sterilization, endoscopes typically are rinsed with water filtered down to the 0.2 micron (200 nanometer) level. Unfortunately, many viruses, endotoxins, and prions are smaller than 200 nanometers, meaning that they can remain in the water even after filtration. Also, as reported in the articles mentioned above, water and water

filters are known sources of contamination. Even more troubling, however, is the statement by one expert that "there are no independent data in the medical literature that support the production of sterile water (defined as containing fewer than 10^{-6} CFU/ml and fewer than 5 endotoxin units/ml) by passing unprocessed water (that is, un-sterilized water, such as water that flows though a hospital's tap) through a bacterial (e.g., 0.1 or 0.2 micron) filtration system" (See Comments by L. Muscarella (Custom Ultrasonics) on AAMI TIR7:1999, Chemical Sterilants and Sterilization Methods: A Guide to Selection and Use, downloaded from the website myendosite.com). Moreover, there is no related art system that monitors the biological content of filtered water to insure its sterility when used in conjunction with medical item cleaning or sterilization apparatuses.

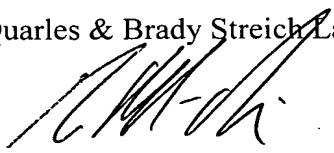
Thus, the present invention involves the use of ozone as a supplemental agent to ensure disinfection and to prevent re-contamination. Given the recent focus on the need to provide an "overkill factor" to prevent re-contamination of endoscopes and medical item processing equipment, the invention more particularly provides for the ozonation of filtered (or unfiltered) rinse water commonly used in existing sterilization systems.

In view of the foregoing, the applicant respectfully submits that the claims of the present invention are distinguishable from the cited art.

No fee is believed to have been incurred for this amendment. Should there be any unforeseen costs, please charge our Deposit Account No. 17-0055.

Respectfully submitted,

Quarles & Brady Streich Lang, LLP



Gavin J. Milczarek-Desai
Reg. No. 45,801

520-770-8716 Phone
520-770-2235 Fax